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**(2) REMARKS**

**Unobviousness**

Claims 1-4 have been rejected under 35 USC §103 as being unpatentable over patent abstract of Japan 10/319358 and patent abstract of Japan 10/108899 for the reasons set forth on pages 2 and 3 of the Office Action of September 24, 2003. That Office Action references the one before it, namely of January 15, 2003, which based the same rejection on the obviousness of adding surface active agents to a contact lens formulation. This rejection is respectfully traversed for the reasons previously given and those stated herein.

The Examiner states that applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention. The examiner states that, although data has been submitted, it is not commensurate in scope with the claimed invention.

**No *prima facie* case of obviousness has been established.**

Applicants first note that they do not concede *prima facie* obviousness. Indeed, applicants do not understand the examiners reasoning for concluding that such has been established.

Three basic criteria must be met to establish a *prima facie* case of obviousness. According to MPEP §2142, they are: (1) there must be some suggestion or motivation (2) there must be a reasonable expectation of success, and (3) the prior art must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

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Applicants note that the first criteria is not met because there are no specific reasons are given in the references themselves or from any presentation of logic as to why someone skilled in the art would be motivated to make the modifications necessary to meet the terms of the claims. There is no reasoning given by the examiner on how the person skilled in the art might be motivated from the deficient teachings of the reference to modify those teachings for applicants' new purpose and new concentrations. There is no logical reason apparent from either the reference or the Office Action as to why the person skilled in the art would put aside the teachings of the reference and adapt those teachings to achieve a purpose not taught other than by applicants' own description.

The Office Action also fails to meet the second criteria. There must be a reasonable expectation of success. The rejection set out by the Office Action calls for changing the teachings of the reference to use less a polyallylamine having allylamine recurring units than its disclosed minimum. There is no reasoning given in the Office Action as to why such a low level would be reasonably expected to work for the disclosed purpose.

Applicants use and claim a polyallylamine having allylamine recurring units at concentrations of 0.3 to 50 ppm. This level of use is not disclosed in the prior art, nor is the reason for its use. JP-A-10-319358 teaches using a polyallylamine having allylamine recurring units as a component for suppressing a change of the basic curve of a contact lens at the time of the distribution in a concentration of not less than 0.01 w/v % (*i.e.*, not less than 100 ppm), preferably not less than 0.1 w/v. These prior art levels are not within the range claimed by applicants. Applicants' maximum level is less than half of what the reference suggests as useful for any purpose. The purpose disclosed by JP-A-10-319358 is very different than applicants' purpose, and there is no sound reason of record why one skilled in the art would attempt to use applicants' levels. That applicant has done so and established an effective low concentration for a different utility, is invention – not optimization.

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From this discussion, it is also apparent that the prior art does not teach or suggest all the claim limitations. It does not teach applicants' concentrations and it does not teach the effect attributed to the low concentration by applicants.

**Applicants' evidence is sufficient in nature and weight to overcome *prima facie* obviousness.**

Applicants have presented evidence of unobviousness sufficient in nature and weight to overcome a rejection based on *prima facie* obviousness, even though *prima facie* obviousness has not been established.

The comments of the examiner fail to address with specifics how applicants' presentation of legal and factual arguments that the data in the Description and Declaration fails to fully rebut the present rejection. Importantly, the basis for the rejection is mere *prima facie* obviousness. As such, evidence of the type presented by applicants should be sufficient to rebut it.

Applicants' have previously called the examiner's attention to the fact that JP-A-1 0-319358 does not teach or suggest that the claimed polyamines, such as polyallylamine, possess an antibacterial activity. This statement has not been rebutted by the examiner. This statement cannot, in fact, be rebutted from the reference teachings.

Applicants' Declaration data is commensurate in scope with their claimed range of 0.3 to 50 ppm. Applicants' data shows effectiveness at levels of 1.2 ppm and 12 ppm. These points are within the claimed range and show significant activity at both points. Another data point, at a point below the claimed range, *i.e.*, 0.12 ppm, no activity is shown. There is no apparent reason to report a test at the level of 50 ppm because the person skilled in the art would not have reason to question effectiveness at this level in view of the data at lower concentrations. See *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Evidence of the unobviousness of a broad range can be proven by a narrower range when one skilled in the art could ascertain a trend that would allow him to reasonably extend the probative value thereof.)

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The previous office actions have been fully silent on the reason why the examiner is asserting that the use of a different level of a polyallylamine for a different purpose makes the claimed different use and different levels obvious. This is clearly not a case where levels are to be optimized. Indeed, without any teaching at all for using the polyallylamine for antimicrobial activity, the level of use for this purpose is not subject to optimization. Simply, one cannot optimize for the unknown. And, obviousness cannot be predicated on what was unknown. See *In re Spormann & Heinke*, 150 USPQ 449 (CCPA 1966). The person skilled the art would not expect that the claimed polyallylamine would exhibit a high antimicrobial activity at concentrations as low as 0.3 to 50 ppm. And, the reference does not say that such low levels would be good for its purposes either. The person skilled in the art does not add materials for no known purpose, and no purpose is given by the reference for using such low levels.

Also, in section 2144.05, the MPEP recognizes that rejections based on routine experimentation are not proper under all circumstances. It states:

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and there-fore the parameter optimized was not recognized in the art to be a result-effective variable.). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (prior art suggested proportional balancing to achieve desired results in the formation of an alloy).

In the present case, the parameter of antimicrobial activity for a polyallylamine having allylamine recurring units was not recognized as a result-effective variable by the prior art. The prior art does not identify the polyallylamine having allylamine recurring units any purpose at concentrations of 0.3 to 50 ppm, and the only effective ranges were, as noted above, of not less than 0.01 w/v % (i.e., not less than 100 ppm), preferably not less than 0.1 w/v %. Applicants do not show simply a lower

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effective concentration for the purposes identified by the prior art, they show a new purpose at concentrations not contemplated by the prior art for any useful purpose.

It is significant that the JP-A 10-319358 reference is directed to a distributing solution (shipping solution) used for preserving contact lenses in distribution process until patients purchase the lens after manufacturing, and that it does not teach or suggest that the polyallylamine has an antimicrobial activity. It is also significant that JP-A-10-319358 teaches that the disclosed distributing solution *may* further contain an antiseptic agent in addition to polyallylamine at a higher level than presently claimed. Simply, the JP-A-1 0-319358 disclosure notes that the polyallylamine is a component in the composition for suppressing a change of the base curve of contact lenses and suggests adding another additive to achieve the very effect which the examiner concludes is obvious. The antiseptic agents disclosed therein are known antiseptic agents such as phenylmercuric nitrate, benzalkonium chloride, hexamethylene biguanide and the like (see paragraphs [0034] and [0035] of the automatic machine translation). JP-A-10-319358 does not teach or suggest that the polyallylamine has an antimicrobial activity. And, a person having ordinary skill in the art reading the reference for what it fairly teaches would draw a conclusion opposite from that of the Office Action. If the person skilled in the art would know to modify the reference teachings as called for in the rejection, then there would be no need to add the further antimicrobial.

JP-A-10-108899 adds nothing to the teachings of JP-A-10-319358 that would bolster the improper conclusion of obviousness.

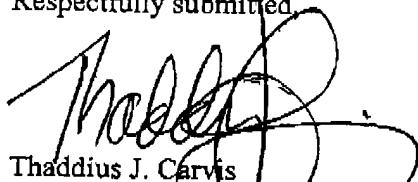
Applicants have made a significant advance in the art and have described it in a manner that clearly distinguishes it patentably from the prior art. In addition, applicants have submitted evidence of unexpected results which is sufficient in nature and weight to overcome a rejection based on *prima facie* obviousness. Accordingly, reconsideration and withdrawal of the rejection and allowance of all pending claims are believed in order, and such actions are earnestly solicited.

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Applicants' representative renews his telephonic request for an opportunity to discuss this application so that the rejection applied can be withdrawn or that the basis for the holding of obviousness can be better understood so that additional data can be obtained and submitted or their appeal can be better presented.

Respectfully submitted,



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